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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097218,213	12/22/98	SCHUTT E	ALLIA.171CPC

021968 HM12/0428
INHALE THERAPEUTIC SYSTEMS INC
150 INDUSTRIAL ROAD
SAN CARLOS CA 94025

EXAMINER
TRAN, S

ART UNIT 1615	PAPER NUMBER
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DATE MAILED: 04/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/218,213

Applicant(s)

Schutt et al.

Examiner

Susan Tran

Group Art Unit

1615



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-51 is/are pending in the application.

Of the above, claim(s) 1 and 13-38 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2-12 and 39-51 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Receipt is acknowledged of applicants' Declaration filed 03/22/99, Verified Statement filed 03/22/99, Corrected Filing Receipt filed 03/22/99, Preliminary Amendment A filed 4/26/99, Information Disclosure Statement filed 05/06/99, Information Disclosure Statement (Supplemental) filed 06/01/99, Statement Establishing Right of Assignee to Take Action filed 02/08/00.

Applicant's election with traverse of Groups I, III and IV in Paper No. 10 is acknowledged. The traversal is not found persuasive because Groups II and III do not require the nebulizer of Groups I and IV. Persuasive is only on Groups I and IV (claims 2-12, and 39-51) as being drawn to a single elected invention

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-29, and 30-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2-12, and 39-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull et al. USPN 6,041,777 ('777), in view of Hanes et al. USPN 5,855,913 ('913).

Faithfull teaches a methods and apparatus for closed-circuit ventilation for pulmonary administration of fluorochemicals agents, bioactive agent, and pharmaceutical agent (column 6, lines 19-47). The closed-circuit ventilation further comprising a nebulizer in the fluid-conducting reservoir, which may be used to introduce aerosols, mists, sprays or to deliver liquid medium, i.e. fluorochemicals to the gas flow path (column 16, lines 27-55). The bioactive agent comprising antibiotics, anti-inflammatories, cardiovascular agents, protein, and surfactants (columns 25 and 26).

Faithfull teaches the use of surfactants, however fails to specifically teach phospholipid surfactant as in the claims.

Hanes teaches a pulmonary drug delivery comprising biodegradable particles having density less than about 0.4 g/cm^3 , and L- α -phosphatidylcholine dipalmitoyl ("DPPC") as a surfactant (columns 4 and 5). The particles can be in single and double emulsion, phase separation or spray drying (column 6, lines 60-67), and the microspheres or particles used in this drug can be in different diameter sizes ranging from about 1-1000 μm , and the mean diameter of at least about $5\mu\text{m}$ (columns 7 and 8). Column 9, lines 15-20 discloses particle having mean aerodynamic diameter size greater than approximately $1 \mu\text{m}$. The bioactive agents comprising polysaccharides, antibiotics, peptides or proteins in the aerosol form, and to be administered to the respiratory system (column 10, lines 4-60).

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Absent unexpected results, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the pulmonary drug delivery system by Faithfull with the use of the phospholipid surfactant of Hanes to obtain the claimed invention. The reason for this modification is to improve the aerosolization of the particles and to reduce particle agglomeration, thus promote absorption of a drug and increase bioavailability of the drug in the lung.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600